

REMARKS

Claims 1-37 and 47-54 are pending in this application. Claims 38-46 are cancelled. Claims 25-37 and 49-57 are withdrawn. Applicant respectfully requests reconsideration of the pending claims, in view of the claim amendments above and the following remarks.

Claim Objections

Claim 1 was objected to because of some informalities. Applicant has now corrected these.

Claim Rejections - 35 USC § 112

Claims 1-24 and 47 and 48 stand rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

Applicant has now added the step of "to provide electrical pulses to one or both vagus nerves", in the independent claims.

Claim Rejections - 35 USC § 102(b)

Claims 1, 2, 4, 8, 9, 11-13, 15-19, 21-23, 47 and 48 are rejected under 35 U.S.C. 102(b) as being unpatentable over Adkins et al. (US 5,928,272). This rejection is respectfully traversed.

In support of the rejection, the Examiner stated on page 5, "Adkins provides an implanted stimulator 10 with an implanted pulse generator module 33 an

implanted stimulus receiver module 40. Adkins further provides an external stimulator 18 that is inductively coupled to the implanted stimulus-receiver 40, as shown by the inductor symbol 40 in figure 2".

Applicant respectfully submits that as clearly shown in FIG. 2, item 33 is a voltage regulator not an implanted pulse generator module. Item 40 is a built in antenna for changing programs and not an implanted stimulus receiver for providing pulses to tissues with an external stimulator. And, item 18 as clearly shown in FIG. 1 is a programming wand and not an external stimulator.

Applicant's independent claims comprises limitations including,

- "implanted stimulator comprising an implanted pulse generator module and an implanted stimulus-receiver module";
- "an external stimulator adapted to be inductively coupled to said implanted stimulus-receiver module"; and
- "controlling means for selectively operating one of said implanted pulse generator module and said implanted stimulus-receiver module".

There is simply no disclosure or even a suggestion in the Adkins '272 patent for any of these claimed limitations. For a reference to anticipate a claimed invention, the reference must enable production and use of a device or method that meets each and every limitation of the rejected claims(s). Adkins '272 simply does not do that.

On page 5 of the Office Action the Examiner further stated, "The external stimulator 18 is thus wirelessly networked for bi-directional communications with the implanted stimulator in order to manage and optimize the patient's therapy,...".

Applicant respectfully submits that there is no disclosure or even a suggestion in Adkins '272 to have an external stimulator which is inductively coupled to an implanted stimulus-receiver (as in claim 1) to provide electrical pulses, or an external stimulator that is networked as, in claim 47. In the applicant's disclosure, support for external stimulator and telemetry unit which is networked is found on pages 30-36 of the specifications in conjunction with FIG. 38-41, 42A, 42B, 43-44, 45A, 45B, and 46-49.

Applicant also asserts that a *prima facie* case of anticipation has not been established. MPEP 2131 states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" (emphasis added). Adkins '272 does not describe every element of the amended independent claims as set forth in the claims. As required by MPEP 2131, Adkins '272 does not show the identical invention in as complete detail as is claimed, and the Adkins '272 system does not have elements arranged as required by the claims.

The present independent claims 1, 15 and 47 require elements listed in the previous pages. Adkins '272 simply does not teach or suggest these claimed elements.

Applicant submits that the disclosure of the Adkins '272 is totally different than the applicant's inventive concept, and further Adkins '272 taken as a whole teaches away from the applicant's disclosure.

The Adkins '272 patent is generally directed toward improvements in automatic activation of an implanted neurostimulator device, particularly for treating epilepsy. As stated in the reference, a principal objective of the invention is to

provide apparatus and methods for activation of an implanted stimulus generator for treating epileptic seizures by sensing changes in certain physiological parameters which can be a reliable precursor of an oncoming attack. According to the invention, the patient's cardiac activity is monitored, preferably by an implanted device, for characteristics of a sudden time rate of change of heart rate not physiologically consistent or compatible with physical exercise. If such a time rate of change is detected, together with a substantial, sustained change, in heart rate, the device is arranged to respond with neurostimulation

In contrast, the Applicant's invention is generally directed to systems and method that provide, among other things, electrical pulses to said nerves to treat (or alleviate symptoms of) obesity and eating disorders, and also function as a conduit for electrical pulses provided by an external stimulator for such therapy. Furthermore, the system can switch between the two modes of stimulation. Cited references simply do not provide the functionality of the Applicant's invention.

Claims 2, 4, 8, 9, 11-13, 16-19, 21-23, and 48 also stand rejected based on 35 USC § 102. Applicant submits that these claims are dependents of now patentably distinct independent claims 1, 15 and 47, and inherit all the limitations of their respective independent claims, and should be allowable, at least, because of their dependence from claims 1, 15 and 47.

Claim Rejections - 35 USC § 103

Claims 3 and 5-7 stand rejected under 35 USC § 103(a) as being unpatentable over Adkins in view of Barrett et al. U.S. 2002/0087192.

Applicant respectfully traverses the rejection. Claim 3 and 5-7 depend directly or indirectly on independent claim 1 and inherit all of the limitations of independent claim. Therefore, applicant submits that claims 3, and 5-7 are allowable, at least, because of their dependence from claim 1.

Further, as noted in the abstract line 5, "...with an electrical pulse signal generated by an implantable neurostimulator ...", whereas, in the applicant's disclosure and claimed combination, the electrical pulse signal may be generated by an implantable neurostimulator or an external stimulator and delivered in conjunction with an implanted stimulus-receiver.

Claims 10, 14, 20 and 24 stand rejected under 35 USC § 103(a) as being unpatentable over Adkins in view of Mann et al. US2002/0055761.

Applicant respectfully traverses the rejection. Claims 10, 14, 20 and 24 are dependents of independent claims 1 and 15 and inherit all the limitations of their respective independent claims. Therefore, applicant submits that claims 10, 14, 20 and 24 are allowable, at least, because of their dependence from claims 1 and 15.

Further, applicant submits, there is no disclosure or even a suggestion in either Adkins or Mann to program the implanted stimulator using only a magnet.

Regarding claims 14 and 24, applicant submits that Mann '761 is generally directed to microstimulators which are designed to be injectable and generally are dependent upon external devices except for a few hours. In addition to the references failing to teach or suggest all the claim limitation, the Mann et al. reference also teaches away from the present invention. As instructed per MPEP 2143.03 (emphasis in original):

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.

A reference teaches away " when a person of ordinary skill, upon reading the reference,...would be led in a direction divergent from the path that was taken by the applicant. "*In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994). The Mann et al. reference leads in a direction different than the direction of the claimed invention.

Conclusion

In view of the claim amendments and forgoing remarks, it is respectfully submitted that the rejections have been overcome and the pending claims are in condition for allowance. An indication of allowability of pending claims is earnestly solicited.

If there are any significant concern's regarding the pending claims, the Applicant requests an interview with Examiner.

Further, if the Examiner has any comments or suggestions which could place this application in even better form, or if the Examiner feels that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,



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